REMARKS

Applicants thank the Examiner for his courtesy in granting the Examiner interview held on July 2, 2003.

Claims 56-85 are pending in the application and have been rejected under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph, as not supported by a credible asserted utility or a well established utility. The rejection was based on the assertion that the invention is directed, not to an assay method, but to a nuclear co-regulatory protein itself which has no disclosed function other than to carry out research to identify its biological function or possible diseases with which it may be associated.

The claims have been amended herein for the sake of clarity. The previous claims and the claims as amended are method claims. The claims are not directed merely to a nuclear co-regulatory protein for use in investigational research to determine what diseases might be affected by a group of unknown nuclear hormone receptors. Known nuclear hormone receptors also may be used with the invention, therefore the well-known relationships between nuclear receptor co-regulatory proteins and the various disease states associated with them and their cognate nuclear hormone receptors and their functions (see previous responses) form the basis for a clear "real world utility." The claims recite a "screening method" and contain clear method steps. The claimed screening method involves screening for a pair of molecules (one of which is a nuclear hormone receptor protein molecule, the other of which is a ligand for the nuclear hormone receptor) that interact with a nuclear receptor co-regulatory peptide molecule based on binding with the binding region of SEQ ID NO:5.

One utility of the method is that once it is learned from the screening method that a particular nuclear hormone receptor-ligand pair interacts with co-regulatory proteins having the binding sequence of SEQ ID NO:5, then the identified ligands can be used to modify the activity of the nuclear hormone receptor. Furthermore, the assay can be used to identify other ligands that also interact with the nuclear hormone receptor and co-regulatory protein. The ligands, identified as interacting via the newly discovered binding sequence (SEQ ID NO:5), can be used as drugs that act on this system or as lead compounds in the well-known modern methods of drug discovery. All of this would be clear to a person of skill upon reading the specification and claims.

It also is known to the person of skill that nuclear hormone receptors and their function are keys to many different disease states that can be and already are being treated by ligands which modify their activity. For example, in hormone-dependent cancers such as breast cancer and prostate cancer, nuclear hormone receptor activation (estrogen and testosterone, respectively) is a key to both disease etiology and treatment. See Tenbaum and Baniahmad, *Int. J. Biochem. Cell Biol.* 29(12): 1325-1341, 1997 (attached). Hormone control therapy is a mainstay of prostate cancer treatment. Further examples of diseases treated with nuclear hormone receptor ligands include thyroid hormone receptor (hypothyroidism), vitamin D receptor (retinoblastoma), glucocorticoid receptor (rheumatoid arthritis) progesterone receptor (breast cancer) and retinoic acid receptor (retinoblastoma).

Therefore, it would be clear to anyone of ordinary skill in the art that ligands which bind to and/or interact with such nuclear hormone receptors could be used to modify the activity of these nuclear hormone receptors for the purpose of modifying the

corresponding disease states. As the Office points out, the assay can be used to identify new, not previously known nuclear hormone receptors. This utility is in addition to discovering new ligands which interact with known nuclear hormone receptors that have known roles in the etiology and treatment of important diseases. The specification and claims as originally filed clearly disclose that known nuclear hormone receptors (having known links to disease states) are contemplated for use with the inventive methods. See, for example, Examples 2 and 4 and original claim 47.

The fact that one utility of the invention is not recognized as a "real world utility" by the Office does not destroy the other utilities of the invention. An assay method for identifying compounds that have a substantial utility define a "real world" context of use, and do not constitute a mere research tool with no utility outside the theoretical context. See M.P.E.P. § 2107.01. The present invention can be used, as disclosed, by the person of ordinary skill in the art in a manner which provides a benefit to the public and therefore meets the requirements of 35 U.S.C. § 101. The present invention therefore possesses a substantial and real world utility that would be apparent to any person of skill in heart upon reading the disclosures.

Applicants therefore request that the Office withdraw the rejection of the claims as currently presented under 35 U.S.C. §§ 101 and 112, first paragraph on the basis of lack of utility.

Claims 56-85 have been rejected under 35 U.S.C. §112, first paragraph, as not sufficiently described in the specification to convey to the skilled person that the inventors had possession of the claimed invention at the time of filing.

Applicants have amended the claims herein, canceling claims 56-85 and rewriting them as new claims 86-94. These rewritten claims are directed to methods for identifying a pair of molecules that interact with a PNRC molecule via the binding sequence of SEQ ID NO:5. Applicants believe that these claims more clearly set out the metes and bounds of the invention desired to be claimed and provide clear method steps.

As discussed in the Examiner interview, the preamble of the independent claims avoids the open claim language "contains" and specifically recites that the interaction with the PNRC molecule is via the binding sequence of SEQ ID NO:5. Applicants believe that these claims are fully supported by adequate written description.

The Examiner is directed to the specification at page 2, line 29 - page 3, line 5, which define PNRC and describe a credible and real-world use for the inventive methods, page 3, line 6 - page 4, line 2, which describe the methods in general terms, page 9, lines 8-11, which refer to the two-hybrid assay, page 10, lines 27-28, which teach a PNRC bait system in a two-hybrid assay, and the examples, which describe methods for performing two-hybrid assays using PNRC molecule bait in yeast and mammalian cells. In addition, these types of two-hybrid assays are recognized by those of skill in the art and can easily be performed with the guidance provided in the specification. The entire sequence of PNRC is provided in the application as originally filed. Therefore, Applicants respectfully submit that the claims are described in their full scope such that no skilled person would doubt that the inventors had possession of the invention at the time of filing.

Applicants therefore request that the rejection on the grounds of lack of written description be withdrawn and the

application proceed to issue. If the Examiner believes that any issues remain to be resolved, he is invited to telephone the undersigned.

RESPECTFULLY SUBMITTED,			
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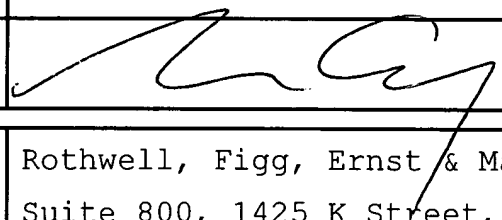
SIGNATURE		DATE	September 8, 2003

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